Food and Drug Administration
Center for Drug Evaluation and Research
Anti-Infective Drugs Advisory Committee
December 10, 2009

Questions for the Committee

VOTE: Has the Applicant provided substantial evidence of the efficacy and safety of 75 mg three times daily of AZLI for the requested indication of improvement of respiratory symptoms and pulmonary function in cystic fibrosis patients with *Pseudomonas aeruginosa*? In your response, discuss the rationale for your answer.

a. If you voted YES, are there any specific issues that should be addressed in labeling?

b. If you voted NO, what additional information is necessary?

VOTE: Has the applicant identified the correct dose and regimen for AZLI for the requested indication? In your response, discuss the rationale for your answer and discuss if there is any additional information that should be generated regarding the dose and regimen.